

Department of Labor and Industries
Office of the Medical Director
Health Technology Assessment Brief
ERMI Flexionaters and Extensionaters

Company: ERMI, Inc.

Products: Knee Ankle Flexionater, Shoulder Flexionater
Knee Extensionater, Elbow Extensionater

Purpose: The devices are intended to increase range of motion after injury or surgery by using a patient-controlled, load application and quick release mechanism.

The Extensionaters use pneumatic systems while the Flexionaters use hydraulic systems. The Knee Ankle Flexionater provides up to 500 ft-lbs of torque at 1-degree increments.

FDA Status: Class I, registered and classified as “Exerciser, non-measuring”

Product Comparison:

	ERMI	Dynasplint	Joint Active Systems
Purpose	Patient Actuated Serial Stretch (PASS). Patient varies load for 1 to 5 minutes of stretch followed by equal duration of joint recovery until 15 minutes elapses.	Brace provides constant load to the joint in the direction of stretch.	Static Progressive Stretch. Brace forces joint into a specific degree of flexion. The load on the joint is reversed at the end of a session.
Load	Low to High	Low	Low
Duration of use	15 minutes, 4 to 8 times per day for approximately 4 to 6 weeks	8 to 12 hours per day.	30 minutes up to 3 times per day.

Evidence: No studies on ERMI products have been published.

Branch, T, et al. "Non-operative Management of the Loss of Knee Flexion After Surgery." Unpublished. 2000.

Rating	Primary Outcome	Inclusion	Exclusion	Baseline Pop Char	Assessor Blinded	Intention to Treat
Class IV - prospective case series	biomechanical functional range of motion defined as 117 degrees of flexion. Patients followed until full or satisfactory ROM achieved, or surgical manipulation required.	>10 degree extension loss with >25 degree flexion loss with tight patella OR >10 degree extension loss with >30 degree flexion loss patella infera. Failed minimum 6 weeks of physical therapy.	Not Reported	96 subjects: average age 42.7 years, average 24.3 weeks from index surgery to use of device.	No	No

Results

Index Procedure or Injury	Number of subjects	Weeks since Surgery	Initial Flexion	End Flexion	Time on Mobilizer
ACL	49	12.2	86	134.7	4.4
Total Knee Arthroplasty	10	10.8	80	120.1	5.2
Extensor Injuries	6	49.4	63.7	127.7	6.7
Fractures	15	12	62.5	131.7	5.8
Miscellaneous	16	14	76	132	6.6

Costs: In 2003, ERMI submitted a request to establish unique HCPCS codes for its products. Until codes are granted, bills are submitted using:

- L2999, "Lower extremity orthoses, NOS", for the Knee Extensionater.
- L3740, "EO, double upright with forearm/arm cuffs, adjustable position lock with active control, custom fabricated", for the Elbow Extensionater.
- E1399, "Durable medical equipment, miscellaneous", for the Knee Flexionater.
- E1399, "Durable medical equipment, miscellaneous", for the Shoulder Flexionater.

ERMI reimburses patients who do not gain range of motion.

Product	In-Network Rental	In-Network Purchase
Knee/Ankle Flexionater	\$88 per day	
Shoulder Flexionater	\$88 per day	
Knee Extensionater		\$460
Elbow Extensionater (custom orthotic)		\$1,460
Set-up fee		\$100

LNI Claims: In 2002, LNI accepted 227 contracture of joint cases according to the following diagnosis codes.

Code	Description	Number of Cases
718.40	site unspecified	10
718.41	shoulder region	33
718.42	upper arm	36
718.43	forearm	20
718.44	hand	63
718.45	pelvic region and thigh	4
718.46	lower leg	41
718.47	ankle and foot	18
718.48	other specified sites	1
718.49	multiple sites	1

HCPSC Code	Description	Number of Cases	Average Charged Amount	Average Allowed Amount	Frequently Associated Diagnosis Code
E1800	Dynamic adjustable elbow extension/flexion device	12	\$331.29	\$331.29	718.42
E1805	Dynamic adjustable wrist extension/flexion device	16	\$411.33	\$411.33	718.43
E1810	Dynamic adjustable knee extension/flexion device	9	\$276.15	\$276.15	718.46
E1815	Dynamic adjustable ankle extension/flexion device	1	\$1,210.00	\$1,210.00	718.47
E1825	Dynamic adjustable finger extension/flexion device	12	\$75.83	\$75.83	718.44
E1830	Dynamic adjustable toe	1	\$335.00	\$335.00	718.47

	extension/flexion device				
	Dynamic adjustable shoulder				
E1840	extension/flexion device	6	\$600.00	\$600.00	718.41

Insurers:

	ERMI	Dynasplint	Joint Active Systems
Blue Cross Blue Shield of New York		BCBS of NY covers Dynasplint for period following subacute injury or postoperatively. Not covered for chronic contractures, chronic stiffness, or for more than 3 months. (4/02)	
Aetna	Aetna does <u>not</u> cover flexionators and extensionators because they are considered experimental and investigational.	Aetna covers dynamic splinting devices if used 1) as an adjunct to PT in patients with significant motion stiffness/loss in the sub-acute injury or post-operative period, OR 2) in the acute post-operative period for patients who have a history of motion stiffness/loss and are having additional surgery or procedures done to improve motion to that joint. Aetna does <u>not</u> cover the prophylactic use of dynamic splinting for chronic contractures (no significant change in motion for a 4-month period) and joint stiffness due to trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy or cerebral palsy.	Aetna does <u>not</u> cover JAS splints (e.g., JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) because there is insufficient evidence in the peer-reviewed published medical literature concerning their safety and effectiveness.
Regence	Regence covers “Mechanical Devices for Joint Stiffness and Contracture” for up to 8 weeks when used for: 1) Joint stiffness caused by immobilization, 2) Established contractures when passive ROM is restricted, or 3) Healing soft tissue that can benefit from constant low-intensity tension. (12/02)		